NIMH
National Institute of Mental Health

NATIONAL INSTITUTE OF MENTAL HEALTH, NIH
REQUEST FOR PROPOSAL - SOLICITATION COVER PAGE

REQUEST FOR PROPOSAL NO:	NIMH-02-DB-0005
TITLE:	*NIMH Program for Toxicological Evaluation of Novel Ligands*
OMB No.: 0990-0115	**PURCHASE AUTHORITY:** Public Law 92-218 as amended; Note: The issuance of this solicitation does not commit the Government to make an award, or to pay any costs for the preparation and submission of a proposal.
ISSUED BY: Bruce E. Anderson Contracting Officer Contracts Management Branch National Institute of Mental Health, NIH Neuroscience Center Building 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD 20892-9603 **POINT OF CONTACT:** Bruce E. Anderson E-mail: ba9i@nih.gov Phone (301) 443-2696 or 2234 Fax at (301) 443-0501 Collect calls will not be accepted.	**ISSUE DATE:** February 22, 2002 **DUE DATE: April 23, 2002** **4:00 p.m., local prevailing time** Note: The official Point of Receipt for the purposes of determining timely delivery is the Contract Management Branch, NIMH. A paper copy with original signatures is the official copy for recording timely receipt. If the Contracting Officer or Designee does not receive your proposal at the place and time specified, then it will be considered late and handled in accordance with PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this solicitation. Facsimile submissions are not acceptable.
NO. OF AWARDS: **PERIOD OF PERFORMANCE:**	One (1) Three (3) years, beginning on or about September 30, 2002, with two (2) one-year options to extend (total 5 years)
SMALL BUSINESS/ 8(a) SET-ASIDE:	No, NAICS Code 541710 Size Standard: 500 employees
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Attachment 4)
TECHNICAL PROPOSAL PAGE LIMITS: **AWARD WITHOUT DISCUSSIONS:**	No The Government anticipates making an award after conducting negotiations, but reserves the right to make an award without discussions

NOTE: OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIMH WEBSITE AT http://www.nimh.nih.gov/grants/indexcon.cfm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. THIS OFFICE WILL PROVIDE NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS.

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

February 22, 2002

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-02-DB-0005 entitled "*NIMH Program for Toxicological Evaluation of Novel Ligands.*"

The documents included with this electronic RFP package are as follows:

I. Streamlined RFP:
   A. Statement of Work (SOW) **(Attachment 1)**
   B. Evaluation Factors for Award **(Attachment 2)**
II. Standard RFP Instructions and Provisions **(Attachment 3)**
III. Applicable RFP References/Forms/Weblinks **(Attachment 4)**

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition. Special attention should be directed to the technical and business proposal instructions contained in **Attachment 3.** The Attachment 3 instructions are very detailed, and some of the information may be superfluous. If you need assistance with these instructions, please contact the undersigned.

In summary, your proposal should consist of:

1. Technical Proposal – see detailed instructions in **Attachment 3; the technical proposal should be formatted in accordance with the outline presented on pages 55-57, of this RFP;** carefully review the requirements in Statement of Work **(Attachment 1)**, and the Technical Evaluation Criteria **(Attachment 2)**; include these forms linked in **Attachment 4:** Technical Proposal Cover Sheet, Technical Proposal Cost Summary, Summary of Current and Proposed Activities. Include information on satisfying the Mandatory Qualification Criterion **(see Attachment 2)**, and submit sample protocols to enable the reviewers to evaluate your ability to perform the required assays **(see Attachment 2).**

2. Business Proposal – see detailed instructions in **Attachment 3**; the business proposal can be submitted in the offeror's own format, but it must show detailed costs, by individual (with hrs./ percent effort) and by cost category, by year, with an accompanying narrative explanation and justification stating how the costs were estimated, i.e., the basis of the estimated costs; **Costs should be based upon providing the Final Compound Report for each compound and species tested ~ 4 weeks after completion of the laboratory work specified in the protocol.**

   In addition to providing yearly costs by cost categories (i.e. labor, fringe benefits, supplies, etc.), it is required that costs also be provided *by type of assay and animal model*. This is not intended to be a fixed-price contract and the estimated assay costs will not be used as the basis for billing.

However, this information may be used for a preaward cost analysis, and also for planning purposes during contract administration. Please complete the Estimated Cost Per Assay Chart in **Attachment 4;** include these linked forms in **Attachment 4**: NIH-2043, Proposal Summary and Data Record; Disclosure of Lobbying Activities, OMB SF-LLL (one copy), Representations and Certifications (one copy). The business proposal should also include information on past performance

An official authorized to contractually bind your organization must sign the proposal. One (1) original and ten (10) copies of your technical proposal, and one (1) original and five (5) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN **4:00 p.m.**, **local prevailing time, on Tuesday, April 23, 2002**, at the following address:

If using overnight delivery service	If using U.S. Postal Service
Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Rockville, MD **20852**-9603	Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD **20892**-9603

Your attention is further directed to the "Proposal Intent Response Sheet" contained in **Attachment 4**. Please complete this form and return it to this office or notify me at the following Internet address: ba9i@nih.gov on or before April 2, 2002. This will allow us to expedite preparations for the peer review of proposals.

Questions concerning any areas of uncertainty, which in your opinion require clarification or correction, must be furnished in writing (Fax or email is acceptable) to Bruce E. Anderson, and marked "Offeror's Questions, RFP No. NIMH-02-DB-0005 ".

Sincerely,

/s/

Bruce E. Anderson
Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Attachments: 1-4

ATTACHMENT 1
February 22, 2002
[Return to TOC]

STATEMENT OF WORK

TITLE: NIMH TOXICOLOGICAL EVALUATION OF NOVEL LIGANDS PROGRAM

Background:

Recent meetings of the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and professional societies in the fields of neuroimaging and drug development have highlighted the emerging interest in molecular imaging as a tool in basic research, drug development, and clinical trials. Positron emission tomography (PET) and single photon emission computed tomography (SPECT) approaches hold promise for understanding *in vivo* biochemistry and physiology in experimental animals and in humans. Imaging approaches have the potential to serve as powerful diagnostic tools and to identify molecular targets in the pathophysiology of mental disorders. In addition, imaging markers can be used to assess disease progression, to identify optimal times for preventive and treatment interventions, and to monitor the progress of treatment. In drug discovery and development, PET imaging is increasingly being used to determine the effects of a drug or drug candidate on the desired target, including dose occupancy relationships (e.g. dose and schedule of administration), the delivery of the drug to a specific target, and drug pharmacokinetics. The translation of imaging approaches in clinical trials research holds the promise of identifying quantifiable markers (surrogates) that can substitute for measures of clinical outcome. Ultimately, validated imaging markers will be used to assess efficacy of novel therapeutic agents, and to guide therapies (e.g., as tools to predict clinical response or adverse effects).

At the recent workshop, "Consortium for the Development of Novel PET and SPECT Ligands for Brain Imaging," academic investigators identified lack of support for toxicological testing of novel compounds for PET and SPECT imaging as one of the key obstacles in radiotracer development (summary available at http://www.nimh.nih.gov/research/imagingsummary.cfm).

The purpose of the NIMH Toxicological Evaluation of Novel Ligands Program is to accelerate the discovery, development, and application of novel ligands for PET, SPECT, and fMRI in humans. The program will also facilitate the discovery and development of novel psychoactive agents for clinical research and as potential therapeutic agents for the treatment of mental disorders. This initiative will provide a critical resource that complements NIMH's existing Psychoactive Drug Screening Program for pharmacological characterization of novel compounds in binding assays for receptors, channels, and transporters in the central nervous system and in biochemical assays to assess functional activity (http://pdsp.cwru.edu/pdsp.htm). The Toxicological Evaluation of Novel Ligands Program will also complement the recent initiative to accelerate the Development of Novel PET and SPECT Ligands for Brain Imaging (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-02-003.html) for use in human studies. Efforts of these activities will be coordinated to establish a pipeline for the rapid and cost-effective development of novel ligands for clinical studies of mental disorders.

Goals and Objectives:

The goal of Toxicological Evaluation of Novel Ligands Program is to assess the toxicology and safety of promising, target-selective compounds for use in human studies. It is anticipated that NIMH-approved and coded samples will be submitted from a variety of sources including NIH-funded research programs, pharmaceutical companies, biotechnology companies, or other sources. Toxicology and safety data

generated from this program will be used by investigators in support of an Investigation New Drug (IND) application or for Radioactive Drug Research Committee (RDRC) evaluation of the compound for human studies. In cases where the compound shows toxicity at doses within the range anticipated for human use, the data will provide investigators with valuable information upon which to base further development of structural analogs.

The objective of the contract is to evaluate acute toxicity and safety of compounds submitted for testing which may include, but are not limited to, novel chemical entities, structural analogs of compounds with an IND, or analogs of FDA-approved drugs. In some cases, compounds will be evaluated for toxicity and safety under conditions of repeated administration.

Independently, and not as an agent of the federal government, the contractor shall furnish all necessary labor (qualified and experienced personnel), services, equipment, materials, supplies, and facilities, except as otherwise specified herein, as needed to perform the work set forth below. The GPO whose position is defined in Section G of this contract shall monitor all work under this contract.

STUDIES TO BE PROVIDED:

A. General Requirements

ITEM 1. The Contractor shall develop experimental protocols in consultation with the Government Project Officer (GPO) and/or FDA staff and conduct studies using established techniques, study parameters, and statistical methods of data analysis in accord with current FDA GLP regulations for nonclinical laboratory studies (21 CFR Part 58) http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr58_01.html) and International Conference on Harmonisation (ICH) Guidelines. Investigators will use the technical reports (Final Compound Reports) as part of an IND, RDRC, or NDA application for human studies. As such, it is required that the format and content of the technical report (Final Compound Report) conform to the highest scientific standards.

ITEM 2. During the contract term, the Contractor shall maintain compliance with current GLP regulations during the contract term, and provide documentation to the GPO of any FDA data audits and inspections (i.e., reports and responses to issues raised) in a timely manner.

If it is determined that problems are encountered with the assays or documentation because GLP conditions were not met or maintained, the Contractor shall repeat the assay at no additional cost to the Government.

ITEM 3. The strains and species used for the in vivo studies shall include: CD-1, C57/BL6, or similar strain of mice; Sprague-Dawley rats; New Zealand white rabbits; purpose bred Beagle dogs; and/or Rhesus monkeys. The animals shall be obtained from an AAALAC-accredited registered breeder (Association for Assessment, Accreditation, and Laboratory Animal Care, U. S. Department of Agriculture (USDA).

ITEM 4. The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of Laboratory Animal Welfare (OLAW) (http://grants.nih.gov/grants/olaw/olaw.htm), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of

Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance. The Contractor shall also be fully accredited by AAALAC. The Contractor's Institutional Animal Care and Use Committee (IACUC) shall approve all animal procedures under this contract. The Contractor shall provide reports of any USDA inspections to the GPO during the contract term, in a timely manner.

B. Specific Technical Requirements

ITEM 5. Outline of Request, Sample Receipt, and Sample Testing Process

The chronological procedure for processing requests for assays, developing protocols, and the sample testing process, can be summarized as follows:

- Investigator contacts Contractor or GPO about submitting compounds to the program for testing
- Investigator obtains Assay Request Form from NIMH or Contractor web pages
- Investigator forwards completed Assay Request Form to GPO and Contractor
- Contractor appraises compound assay request and forwards recommendations to GPO
- GPO approves, amends, or denies compound testing request based on Contractor's appraisal and on NIMH programmatic considerations
- Contractor sends empty sample vials to investigator at contract expense
- Investigator sends samples to Contractor at own expense and provides Compound Data Sheet
- Contractor stores samples according to specifications
- Contractor develops an experimental protocol for testing the compound in the approved tests and sends draft electronically to GPO and investigator
- Protocol is reviewed by investigator and GPO
- GPO works with Contractor, investigator, and/or FDA to revise the protocol if necessary
- GPO transmits written approval of finalized protocol to Contractor
- Compound is scheduled for testing
- Testing initiated and completed; however, if compound shows toxicity at doses selected, the GPO is consulted; the study and data analysis may be terminated prior to completion and the protocol may be amended
- Raw Data Report and Draft Compound Report for each compound/species tested sent to GPO electronically for review and approval
- If incomplete, GPO will discuss with Contractor to resolve any issues and finalize the report
- GPO transmits written approval of finalized (draft) report
- Contractor prepares a signed copy of the Final Compound Report certifying that the studies were conducted in compliance with GLP regulations
- Contractor provides signed copies of Final Report to GPO and investigator

ITEM 6. Types of assays

Upon request, the Contractor shall be prepared to develop protocols for approval, and upon protocol approval conduct the following types of assays:

Assay 1. Acute, Toxicological Evaluation of Ligands for Brain Imaging: Acute, Single Dose Toxicity Studies in Accordance with FDA/ICH Guidelines [approximately 15 compounds tested/year]

Requirements and considerations:

a. Contractor shall provide state-of-the-art, toxicological evaluation of coded compounds, as specified by the GPO, in single dose toxicity tests.

b. Single dose toxicity and toxicokinetic studies (GLP required). The Contractor shall develop an experimental protocol for an expanded acute study of the ligand after intravenous (iv) administration in two species (one rodent and one non-rodent) in accordance with the current FDA draft guidance document "Developing Medical Imaging Drugs and Biological Products" dated June 2000 (http://www.fda.gov/cder/guidance/3646dft.htm).

c. Experimental protocol: The Contractor shall consider the following information in developing the experimental protocol for each compound in each species that is used for testing:

- Doses: Control and 3-dose paradigm, or control and single-dose paradigm.
  Control and 3-dose paradigm. Choice of doses is based on no-observed-adverse-effect level (NOAEL) information for the compound. Low dose should be approximately 100x the maximal expected mass dose given to humans in ug/kg); mid dose (1,000x the maximal expected human dose), and high dose (10,000x the maximal expected human dose).
  Single-Dose Paradigm: A single dose (10,000x the maximal expected human dose) may be able to replace the 3-dose paradigm if it has no observable effects on toxicology.
- Species: one rodent (rat or mouse), and one non-rodent species (rabbit, dog or primate). If rabbit is used, justification must be provided based on pKa/receptor binding, or if the pharmacology is closer to humans than either dog or primate.
- Number of animals/group: (N=4-6 males, 4-6 females for rodents or rabbits; N=2-3 for dogs or primates).
- Termination points for experimental measures: (possibly 1), 3, and 14 days after a single iv dose of the unlabeled compound.
- Clinical observations/behavioral effects:

  1. Clinical observations/behavioral effects shall be made daily for 14 days after iv dosing and shall include, but are not limited to, body weight, food consumption, general appearance, behavior, and onset and progression of any signs of toxicity.
  2. Tests may be based on the functional observational battery (FOB) for rats (*Am. Coll. Toxicol.* 15: 239, 1996), a modified Irwin's test (*Psychopharmacologia* 13: 222-257, 1968), or other appropriate tests.

- Clinical histopathology: Necropsy shall be done in control and high dose groups first to identify organs showing toxicity. Any organ showing suspicious lesions shall be subjected to histopathological evaluation. Even if there are no findings at necropsy, 13 or more appropriately selected tissues (key organs, including brain as the target organ, the injection site, and thyroid for iodo- compounds) shall be sectioned, stained histologically, and evaluated for histopathology by a trained histopathologist. Organs showing toxicity in the high dose group should be examined in the low and mid dose groups.

- Blood collection for clinical chemistry and hematology: Blood samples shall be collected at termination for hematology and clinical chemistry analysis. Additional samples shall be collected in "satellite" animals in Assay 2 to complement/augment the sample size and time points as appropriate.
- Opthalmoscopic examination.
- Urinalysis.
- Data analysis. Data analysis for the clinical observations/behavioral effects of the compound shall be done by two-way ANOVA and two-tailed t-tests, Dunnett's t-test for multiple comparisons, or other appropriate statistical tests.

d. The Contractor shall send the draft protocol electronically to the GPO and the investigator for review within 1-2 weeks after receipt of compound and compound data sheet. The Contractor if necessary shall revise the protocol in accordance with recommendations by GPO, investigator, and/or FDA staff.

e. The GPO transmits written approval of final protocol. The Contractor shall initiate the toxicological evaluation of the compound using the approved protocol within 1-2 weeks after protocol approval.

f. The Contractor shall provide a Raw Data Report for each compound and species tested within 1 week of completion of the laboratory work. The report should include a table of individual (raw) data points, and a table and graphic representation of the mean values and time course for each dose of the compound in a given assay/test, and a brief description of the findings (i.e., a determination of whether any of the animal toxicology findings would be considered as possible indications of human risk). Mean $\pm$ SEM shall be determined for each of the values.

g. The anticipated time frame for completion of the Final Compound Report for each compound and species tested is ~ 4 weeks after completion of the laboratory work specified in the protocol. Submission and approval of a *Draft Compound Report* is required prior to the final report. The Final Compound Report shall be structured according to the currently accepted requirements (style and content) necessary for documentation submitted in support of an IND, RDRC, or NDA application. The data collection and statistical analyses shall conform to the minimum standards set by FDA GLP regulations. **The Final Compound Report shall contain a signed statement indicating that the experimental study was conducted in full compliance with current GLP regulations.**

h. The Contractor shall maintain laboratory records, specimens, and raw data from experimental studies in a locked, confidential Archive available for inspection and detailed review by government officials (GPO and FDA).

Assay 2. Acute Toxicokinetic Studies: Acute, Single Dose Studies in Accordance with Applicable FDA/ICH Guidelines [approximately 5 compounds tested/year]

Requirements and considerations:

a. Toxicokinetic studies in two species: The Contractor shall develop an experimental protocol to collect blood samples for an expanded acute toxicokinetic study of the ligand in one rodent (rat) and one non-rodent species (rabbit, beagle dog, or primate) using the highest acute single dose or doses of compound specified in Assay 1.

b. Blood samples. Additional blood samples shall be collected for clinical chemistry and hematological evaluation for any animals/time points necessary to complement data collected in Assay 1. Blood samples (1 cc) for toxicokinetics shall be taken at appropriate intervals (approximately 6 time points) between 5 min and 24 h post-injection based on the known metabolism of the compound. The toxicokinetic study shall be performed in rats and one non-rodent species using the identical acute, single dose or doses of compound protocol approved for use in Assay 1. The samples collected from these "satellite" animals will be staggered across time points so that rats are not sampled more than 4 times (including a terminal plasma sample). Blood samples collected from non-rodent species need not be terminal studies.

c. Compound analysis in plasma: The Contractor shall ship frozen plasma samples (in accordance with Government specifications) to the investigator for analytical analysis of ligand and metabolites. In some cases, the Contractor may be asked to perform the analyses. The samples will be extracted according to methods provided by the investigator. Plasma levels of compound and metabolites in the extracts may be assayed by HPLC, GC/MS, or biological assay (based on detection limits/sensitivity of the assay) to determine the mass equivalent of the compound and metabolites.

d. Liver enzyme metabolic profile: The compound metabolite profile shall be assessed in an in vitro assay using rodent and/or primate hepatocytes followed by LC/MS or GC/MS analysis. Hepatocytes shall be incubated with compound at 37 C. Aliquots of the hepatocyte suspension/sample mixture shall be analyzed for metabolites by either the investigator or Contractor.

e. The Contractor shall provide a Raw Data Report for each compound and species tested (see Assay 1f). The data shall be incorporated into the Final Compound Report for each compound and species tested as specified (see Assay 1g) or, in some cases, prepared as a separate, unique report.

Assay 3. Acute, Safety Pharmacology of Ligands for Brain Imaging: Acute, Single Dose Testing in Accordance with FDA/ICH Guidelines [approximately 5 compounds tested/year]

Requirements and considerations:

a. Cardiovascular function. An expanded acute study of the ligand in dogs or primates (GLP not required).

- Dose: The dose or doses shall be based on the data obtained from the toxicity studies carried out in Assay 1, and may require the use of a lower range of doses.
- Number of animals/group: N=2-3 males, 2-3 females for dogs or primates in a non-terminal setting.
- Clinical observations: examination at baseline and additional time points up to 24 hours.
- Respiration Rate: pre- and post-acute, single dose of compound and at additional time points
- Cardiovascular Measurements: EKG (6 or 10 leads), QT interval, heart rate, blood pressure (systolic, diastolic, mean arterial pressure), and vascular resistance.
- Body Temperature: baseline and additional time points up to 24 hours.
- Renal Function: not required unless there is evidence of toxic metabolites.
- Time points: baseline and continuous EKG up to 1 hour, then additional time points up to 24 hours.

- Protocol: The Contractor shall develop the protocol for review and approval by GPO prior to starting these studies.

b. The Contractor shall provide a Raw Data Report for each compound and/ species tested (see Assay 1f). The data shall be incorporated into the Final Compound Report for each compound and species tested as specified (see Assay 1g) or, in some cases, prepared as a separate, unique report.

Assay 4. Chronic, Toxicological Evaluation of Novel Compounds: Repeat Dose Toxicity Studies in Accordance with Current FDA/ICH Guidelines [approximately 2 compound tested/year]

Requirements and considerations:

a. The Contractor shall develop an experimental protocol to conduct 7, 14, 30, or 90-day repeat dose toxicity studies in rodents (rats or mice) by the route of administration specified by the investigator. The Contractor shall consider the information indicated in Assay 1c in developing the experimental protocol for each compound and species tested.

- Dose: The dose or doses shall be based on the data obtained from acute toxicity studies or on information provided by the investigator.
- Number of animals/group: N=10-15 males, 10-15 females for rodents.
- In-life evaluations should include: body weights (determined daily during the first week, then once weekly, and at termination); detailed physical signs 3 times daily during the first week, then once daily and at termination).
- Collection of plasma samples for hematology and clinical chemistry as specified (*Fund Appl Tox* 29: 198-201, 1996). Plasma samples for determination of test compound on the first and last day that the compound is administered.
- Clinical pathology evaluations on the appropriate # of tissues per animal on all surviving animals at termination as specified by FDA/ICH guidelines

b. The Contractor shall develop an experimental protocol to conduct 7, 14, 30, or 90 day repeat dose toxicity studies in beagle dogs or primates by the route of administration specified by the investigator based on current, applicable FDA/ICH guidelines.

- Dose: The dose or doses shall be based on the data obtained from acute toxicity studies or on information provided by the investigator.
- Number of animals/group: N=3 males, 3 females for dogs or primates, or the numbers specified by current FDA/ICH guidelines.

c. Toxicokinetic Studies in Two Species: The Contractor shall develop an experimental protocol for an a toxicokinetic study of the compound in one rodent (rat) and one non-rodent species (rabbit, beagle dog, or primate) using the highest single dose or 3 doses of compound used in Assay 1, or using the dose/doses specified by the investigator.

d. Blood Samples: Blood samples shall be taken for clinical chemistry (CBC) and hematological evaluation. Blood samples (1 cc) for toxicokinetics shall be taken at 6-8 intervals between 5 min and 24 h post-injection on the first and last day of treatment based on the known metabolism of the compound. The toxicokinetic study shall be performed in rats and one non-rodent species using the identical doses of compound approved for use in Assay 1, or using the dose/doses specified by the investigator.

e. Compound Analysis in Plasma: The Contractor shall ship frozen plasma samples to the investigator (in accordance with Government specifications) for analytical analysis of the compound and its metabolites, or the Contractor may be asked to perform the analysis. The sample will be extracted according to methods provided by the investigator or the GPO. Plasma levels of compound and metabolites in the extracts will be assayed by HPLC, GC/MS, or biological assay (based on detection limits/sensitivity of the assay) to determine the mass equivalent of the compound.

Assay 5. Chronic Safety Pharmacology Testing according to Current FDA/ICH Guidelines (GLP not necessarily required) [approximately 0-1 compound tested/year]

Requirements and considerations:

a. Neurotoxicology, cardiovascular, respiratory, and renal function: The Contractor shall develop an experimental protocol to conduct 7, 14, 30, or 90-day repeat dose toxicity studies in rodents (rats or mice) by the route of administration specified by the investigator. The Contractor shall consider the dose levels specified in the protocol for acute toxicity studies, if applicable, for each compound. More than one species may be indicated for cases with no previous data or when species relevance is difficult to determine. Cell lines from species may predict the choice of species most appropriate for human studies. Safety studies may be required for the following systems and specific target organs: nervous/neurobehavioral (CNS and behavior), cardiovascular (heart and blood vessels), renal (kidney), gastrointestinal and hepatic (esophagus, stomach, intestines, liver), respiratory (lungs and bronchi), blood, endocrine (thyroid and other organs).

b. Neurotoxicology, cardiovascular, respiratory, and renal function: The Contractor shall develop an experimental protocol to conduct 7, 14, 30, or 90 day repeat dose toxicity studies in non-rodent species (dogs or primates) by the route of administration specified by the investigator. The Contractor shall consider the dose levels specified in the protocol for chronic studies in rodents, if applicable, for each compound. Safety studies may be required for the following systems and specific target organs: nervous/neurobehavioral (CNS and behavior), cardiovascular (heart and blood vessels), renal (kidney), gastrointestinal and hepatic (esophagus, stomach, intestines, liver), respiratory (lungs and bronchi), blood, endocrine (thyroid and other organs).

Assay 6. Mutagenicity and Genotoxicity Studies [approximately 0-1 compound tested/year]

Requirements and considerations:

a. The Contractor shall develop a GPO-approved protocol and conduct mutagenicity studies with one or more of the battery of tests in accordance with current FDA/ICH guidelines: e.g., Salmonella Reverse Phase Mutation Assay, Mouse Lymphoma Gene and Chromosomal Mutation assay, CHO Cytogenic Assay, Mouse Micronucleus Assay, and/or Unscheduled DNA synthesis.

b. The Contractor shall develop a GPO-approved protocol and conduct teratology studies in accordance with current FDA/ICH guidelines.

ITEM 7. Estimated Schedule of Work Requirements for Assays 1 through 6

The GPO may request that a combination of assays be done on a given compound approved for testing, or request testing of many compounds in a given assay or set of assays according to the needs of investigators requesting services and NIMH programmatic priorities.

Assume the following assay workload for each year of the contract (actual quantities may vary during the term of the contract):

Type of Tests	Approximate No. of Compounds Tested/Year	*Species*
Assay 1 - Acute toxicology testing	5	Rodents
Assay 1 - Acute toxicology testing	5	Rabbit
Assay 1 - Acute toxicology testing	5	Dog or primate
Assay 2 - Toxicokinetic studies	5	Rats
Assay 3 – Acute safety pharmacology	5	Dog or primate
Assay 4 - Repeat dose toxicology – 30 day	1	Rodents
Assay 4 - Repeat dose toxicology – 30 day	1	Dogs
*****Assay 5 - Repeat dose safety pharmacology	0-1	Dogs
*****Assay 6 - Mutagenicity and genotoxicity	0-1	Cell-based

***[NOTE 1 TO THE OFFEROR: For cost purposes, include a *separate* cost estimate for testing 1 compound in Assay 5 and 1 compound in Assay 6, but do not include these costs in the total proposed cost for the contract.]**

ITEM 8. Option to Extend the Term

The NIMH shall have the unilateral option to extend the performance period of this contract for one or two additional 12-month periods. During each option year, the Contractor shall perform essentially the same work as required for Contract Years 1-3.

[NOTE 2 TO THE OFFEROR: Include costs for each of the two option years in the TOTAL COSTS in the business proposal.]

ITEM 9. Sample Receipt, Storage, and Confidentiality

a. After a compound has been approved for testing by the GPO, the Contractor shall package and ship coded sample vials (according to Government specifications) and Compound Data Sheets to the investigator via overnight express delivery. Shipment of sample vials to investigators shall be paid by the Contractor and charged to the contract. The Contractor shall ensure that the Investigators pay the costs of returning the coded sample vials containing the appropriate amount of compound to be tested, and the Compound Data Sheets.

b. The Contractor shall store samples as specified by the investigator. Samples shall be weighed out not more than one working day prior to evaluation.

c. Investigator's Rights: The Contractor shall protect the investigators' intellectual property rights and patent rights to any proprietary compound submitted for testing, including data, or inventions developed under this contract. This contract includes an approved deviation to the Patent Rights clause at FAR 52.227-11 (see Appendix 1), which shall govern the testing of all proprietary compounds.

[NOTE 3 TO THE OFFEROR: Approval to use a deviation to the standard patent rights clause in (FAR 52.227-11, Patent Rights – Retention By the Contractor-Short Form) is being sought for this contract (see full text of this clause in Appendix 1 to the Statement of Work). Upon approval from the NIH, this clause will be used in any resultant contract. This clause will ensure the confidentiality and protect the intellectual property (IP) and patent rights of an investigator or party supplying a proprietary compound for testing under this contract. If compounds received for testing are already in the public domain, the Contractor will retain patent rights as specified FAR 52.227-11)]

d. Contractor's rights: The Contractor shall assume the intellectual property and patent rights for any invention related to toxicity, safety, and mutagenicity assays, data analysis methodologies, or data management systems developed or modified under the contract with the use of non-proprietary compounds only. The Contractor shall notify the GPO and Contracting Officer 30 days in advance of the submission of any inventions or publications resulting from work done under this contract.

e. The Contractor shall use compounds supplied by investigators under this contract only for contract-related research. The Contractor shall not publish any data generated from investigators' compounds submitted for testing under the contract, without written approval of the GPO. Since the investigator is supplying the compounds, the toxicity and safety data for compounds shall be disclosed only to the GPO and to the investigator.

f. The investigator or party supplying the proprietary compound may request that the Contractor sign a Material Transfer Agreement (MTA) and/or a Nondisclosure/Confidentiality Agreement similar to (or same as) those used by the NIMH (see attached examples in Appendices 2 and 3)

g. All proprietary and non-proprietary compounds submitted for testing under this contract shall be disposed of by the Contractor (according to Government specifications) within 60 days after the compound assays, data analyses, and Final Compound Reports have been completed and approved by the GPO.

ITEM 10. Data Management

a. The Contractor shall maintain a secure, cumulative electronic database of compounds evaluated in toxicity and safety tests in Microsoft Excel for PCs. When a compound is approved for testing, the following entries shall be made: 1) compound identification number or name; 2) source of compound (investigator name affiliation, phone, fax, and e-mail); 3) date of receipt; 4) storage and handling requirements; 5) tests authorized; 6) date when protocol approved; 7) date when study began; 8) date when study completed; 9) date when Raw Data Report is sent to GPO; 10) date when Draft Compound Report is sent to GPO; and 11) date when Final Compound Report is sent to GPO and investigator.

b. World-wide web resources

1) The Contractor shall construct and maintain web pages, approved by the GPO, with information about the NIMH Toxicological Evaluation of Novel Ligands Program. The site shall contain a description of the goals of the program, procedures for submitting compounds for testing, a list of the available toxicity and safety tests, an Assay Request form, and a Compound Data Sheet form. The Contractor shall maintain WWW pages that link to the NIMH's pages and are updated as needed.

2) The Contractor shall make information available about the NIMH Toxicological Evaluation of Novel Ligands Program, at approximately 2 scientific meetings per year (e.g., materials made available at an exhibit booth and at the NIMH exhibit booth for approximately 3 days at the Society for Neuroscience annual meeting).

ITEM 11. Reporting Requirements

a. Raw Data Reports

Each study conducted under this contract shall be carried out according to a GPO-approved experimental protocol. The Contractor shall provide a Raw Data Report to the GPO electronically in Microsoft Word or Excel format for PCs for each compound tested within 1 week after completion of the laboratory work. The report should include a table of individual (raw) data points, and a table and graphic representation of the mean values and time course for each dose of the compound in a given assay/test. Mean $\pm$ SEM shall be determined for each of the values, as appropriate. A brief legend indicating number and sex of subjects should be included for tables and graphs.

b. Draft and Final Compound Reports (Technical Reports)

1) Draft Compound Reports shall be submitted to the GPO electronically in Microsoft Word format for PCs. A Draft Compound Report shall be prepared for each compound and species tested. It should be submitted in a timeframe sufficient to complete the Final Compound Report within ~ 4 weeks after completion of the laboratory work for the study specified in the experimental protocol. The draft report should be structured according to the general requirements (style and content) necessary for documentation submitted in support of an IND, RDRC, or NDA application. The report should include a title page, summary, introduction, methods, results, tables and figures, conclusion, specimen storage and archive record information, and the approved, signed experimental protocol. The data collected and documentation should conform to the minimum standards set by the FDA GLP regulations.

2) The draft report shall be reviewed, assured for quality control, contain a statement certifying that the studies were conducted in compliance with current GLP regulations, approved, signed, and dated by the Contract Project Director. The report shall be submitted to the GPO electronically along with one hard copy. After the draft report is reviewed and approved by the GPO, the Contractor shall finalize the report (it will then be called the Final Compound Report). The Contractor shall send one signed copy of the Final Compound Report to the GPO and one signed copy to the investigator who requested testing of the compound.
3) In the event that quality control/assurance issues arise with compound data in any of the tests performed under the NIMH contract, the Contractor shall cooperate fully with the GPO to resolve the issues, if necessary repeating specified tests or data analyses at no additional costs

to the contract. In the event that compound quality control or assurance issues in a given experimental study can not be resolved between the Contractor and GPO, a scientific advisory group chosen by the GPO shall be asked to review the data and make recommendations to resolve the issues.

c. Weekly Reports

1) Weekly reports shall be submitted to the GPO electronically in Microsoft Word format for PCs on Monday of the following week.

2) The report shall include a brief (1/2-1 page outline) of assay related activities: for example, the testing status of each compound in the approved assay(s), the status of experimental protocols, and status of raw data and draft compound reports for each compound.

d. Monthly Reports

1) The Contract Project Director shall submit monthly reports to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs within 7 calendar days after the end of each calendar month.

2) The report shall include the cumulative summary of the number and type of compounds received to date, source of compound, the testing status of each compound, the status of experimental protocols, and status of raw data reports and draft/final reports for each compound as specified in Item 6, Assay 1, paragraphs f and g.

3) Clear documentation of unsuccessful efforts, unexpected findings, or current problems that may impede progress in any experimental study, actions taken, or proposed.

e. Annual Reports

1) The Contract Project Director shall submit annual reports to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs, along with 2 signed hard copies, within 14 calendar days after the end of each contract year.

2) The annual report shall be compiled to summarize the information contained in that year's monthly reports.

3) The report shall include: 1) the cumulative summary of the number and type of compounds received to date, the testing status of each compound, source of compound, study number and title, status of study (see Item 10, paragraph a); 2) a summary of the results of each completed study on all compounds evaluated for toxicity and safety under the contract; and 3) status of IND, RDRC, or NDA applications submitted for compounds tested under the contract.

f. Final Report

1) The final report shall be submitted in addition to the annual report for the final year.

2) The Contract Project Director shall submit the final report to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs, along with 2 signed hard copies, on or before the effective contract expiration date.

3) The final report shall include an executive summary of all of the compound toxicity and safety studies conducted under the contract.

ITEM 12. Transition to the Subsequent Contractor

a. At least 90 days prior to the contract expiration date, the Contractor shall provide the GPO with a list of all data, including laboratory records, specimens, and raw data from experimental studies, software programs used to interpret or manipulate the data, data collection forms, and compound databases, generated under the contract. At this time, the Contractor shall describe their plans for providing all such archival data, specimens, protocols, reports, and compound database information to a successor contractor or to NIMH.

b. Upon request, the Contractor shall transfer all the above Government property as directed, and fully cooperate with any successor contractor and NIMH to ensure an efficient transfer.

APPENDIX 1
February 22, 2002
[Return to Statement of Work]

52.227-11 Patent Rights (Deviation)

This clause deviation applies to discoveries resulting from routine preclinical and clinical screening, toxicology, or synthesis activities involving the use of proprietary materials (compounds and procedures). Discoveries resulting from research activities pertaining to the development of new assays or the development or modification of chemical synthesis procedures, process development or other unanticipated discoveries developed by the contractor without the use of proprietary materials will be covered by the standard Patent Rights Clause (FAR 52.227-11, Patent Rights – Retention by the Contractor (Short Form) (June 1997)

(a) Definitions.

(1) "Invention" means any invention or discovery, which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, *et, seq*.)

(2) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(3) "Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statue.

(4) "Practical application" means to manufacture, in the case of a composition of matter or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(5) "Small business firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) "Subject Invention" for the purpose of this clause, means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in Section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance. It does not refer to research activities that lead to the development of new screening assays, new toxicological assays, or the development or modification of chemical synthesis procedures, process development or other discoveries not directly related to the scope of this contract. Development of new screening assays, new toxicological assays, or the development of new chemical synthesis procedures, modification of existing procedures, process development or other unanticipated discoveries developed by the contractor without the use of

proprietary compounds will not be subject to the provisions of this deviation but will be covered by the standard Patent Rights Clause which is also incorporated in this contract.

(7) "Compound Suppliers" means any entities or organizations that make available to NIMH a composition of matter or product, patented or unpatented.

(8) "NIMH" means the National Institute of Mental Health of the National Institutes of Health (NIH).

(9) "NIH" means the National Institutes of Health.

(b) *Allocation of principal rights.* (1) Retention of pre-existing rights. Compound Suppliers shall retain all pre-existing rights to those compounds in which the compound supplier has a proprietary interest.

(2) Assignment to the NIH or compound supplier. The contractor agrees to assign to the NIH or to a Compound Supplier designated by NIMH the entire right, title, and interest throughout the world to each subject invention except to the extent that rights are retained by the contractor under subparagraph (b)(3) of this clause and subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States Government to practice or have practiced the subject invention for or on behalf of the United States throughout the world.

(3) Greater Rights Determinations. The contractor, or an employee-inventor after consultation by the NIMH with the contractor, may request greater rights to an identified subject invention of the contract in accordance with the procedures of FAR paragraph 27.304-1(b) and (FAR paragraph 27.304-1(c)) in the case of an employee-inventor). The NIMH will grant greater rights if the supplier is not interested in developing the invention. In addition to the considerations set forth in paragraph 27.304-1(b), NIMH will consider whether granting the requested greater rights will interfere with rights of the Government or any Compound Supplier or otherwise impede the ability of the Government or the Compound Supplier to develop and commercialize new compositions of matter, compounds, product designs, dosage forms, therapies, technologies or other approaches for the treatment of mental disorders in a rapid, efficient, and cost-effective manner. A request for a determination of whether the contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NIMH Contracting Officer at the time of the first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than eight (8) months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13, and to any reservations and conditions deemed to be appropriate by NIMH such as the requirement to assign or exclusively license the rights to subject inventions to the Compound supplier. A determination by NIMH denying a request by the contractor for greater rights in a subject invention may be appealed within 30 days of the date the contractor is notified of the determination to any agency official at a level above the individual who made the determination. If greater rights are granted, the contractor must file a patent application on the invention. Upon request, the contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any subject invention in any country for which the contractor has retained title. Upon request, the contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by contractor.* The contractor will disclose each subject invention to the NIMH Contracting Officer as provided in paragraph (j) within two months after the inventor discloses it in

writing to contractor personnel responsible for patent matters. The disclosure to the NIMH Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(d) *Contractor action to protect the Government's interest. (1)* The contractor agrees to execute or to have executed and promptly deliver to the NIH all instruments necessary to – (i) Establish or confirm the rights the Government has throughout the world in subject inventions pursuant to paragraph b.2. above, and (ii) Convey title to the NIH or to a Compound Supplier when requested under paragraph b.2. of this clause and to enable the NIH or a Compound supplier to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's right or a Compound Supplier's right in the subject inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. The contractor will notify the NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

(3) The contractor agrees to include, within the specification of any United States patent application it files and any patent issuing thereon covering a subject invention the following statement, "This invention was made with Government support under (identify the contract) awarded by the National Institute of Mental Health. The Government has certain rights in the invention."

(4) The contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all subject inventions or stating that there were none.

(e) *Subcontracts.* (1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental, or research work. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's subject inventions.

(2) In the case of subcontracts, at any tier, NIH, the subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and NIH with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in

connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13 which is incorporated by reference in paragraph b.3 of this clause.

(f) *Reporting on utilization of subject inventions in the event greater rights are granted to the contractor.* The contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees when the NIH has granted a request under subparagraph b.3. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the NIH in connection with any march-in proceeding undertaken by the NIH in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the NIH agrees it will not disclose such information to persons outside the Government without permission of the contractor.

(g) Preference for United States industry in the event greater rights is granted to the contractor. Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the NIH upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights in the event greater rights are granted to the contractor. The contractor agrees that, with respect to any subject invention in which it has acquired title through the exercise of the rights specified in subparagraph (b)(3), the NIH has the right in accordance with the procedures in FAR paragraph 27.304-1 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the NIH has the right to grant such a license itself if the NIH determines that—

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) Such action is necessary because the agreement required by paragraph (g) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(i) *Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the contractor.* If the contractor is a nonprofit organization, it agrees that—

(1) Rights to a subject invention in the United States may not be assigned without the approval of the NIH, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided, that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the NIH deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e);

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses, (including payments to inventors) incidental to the administration of subject inventions will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms, and that it ill give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary of Commerce may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the contractor could take reasonable steps to more effectively implement the requirements of this subparagraph.

(j) Communications. All invention disclosures and requests for greater rights shall be sent to the NIMH Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications should be sent to the Office of Extramural Inventions and Technology Resources Branch, OPERA, National Institutes of Health, Rockledge, II, 6701 Rockledge Drive, Room 3190, MSC 7750, Bethesda, MD 20892-7750

(End of Clause)

APPENDIX 2
February 22, 2002
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STANDARD AGREEMENT FOR SUBMITTING COMPOUNDS FOR TESTING

National Institute of Mental Health
Molecular and Cellular Neuroscience Research Branch
Division of Neuroscience and Basic Behavioral Science

THIS AGREEMENT, made and entered into on the _____day of _____, 2002, by and between the National Institute of Mental Health (hereinafter referred to as "NIMH") a component of the National Institutes of Health (NIH); and _____, a corporation having executive offices at _____, (hereinafter referred to as "COMPANY");

WHEREAS, COMPANY is the owner of

_____

(hereinafter referred to as "COMPOUNDS") and certain proprietary information pertaining thereto, which may be useful in the treatment of mental illness;

WHEREAS, NIMH has certain conventional toxicology and safety pharmacology tests (hereinafter referred to as "CONVENTIONAL TESTS") which may be useful in discovering compounds which have activity in the treatment of mental disorders;

WHEREAS, COMPANY wishes to have its proprietary compounds tested by NIMH in CONVENTIONAL TESTS and not administered to humans, and

WHEREAS, the parties wish to enter into arrangements to be used in the confidential testing of COMPANY compounds by NIMH;

NOW THEREFORE, the parties agree as follows:

Article 1. From time to time COMPANY will supply to a facility under contract to NIMH (hereinafter referred to as a "NIMH CONTRACTOR") or to a Government laboratory designated by NIMH, the above-mentioned COMPOUNDS and/or other compositions of matter patented or unpatented, for testing, so that NIMH may evaluate such COMPOUNDS for possible use in the treatment of mental disorders. COMPANY shall have the right to review all protocols used in testing of COMPOUNDS.

Information relating to the COMPOUNDS themselves, including their chemical structure or other identifiers, their physical properties, their biological activity, and the identity of the provider of COMPOUNDS, will be provided to NIMH by COMPANY and appropriately marked as "Confidential" (hereinafter referred to as "COMPANY CONFIDENTIAL INFORMATION"). Information will be generated on COMPOUNDS by NIMH CONTRACTORS using CONVENTIONAL TESTS (hereinafter referred to as "NIMH DATA").

Article 2. In order to facilitate the record keeping and handling of COMPANY CONFIDENTIAL INFORMATION, the parties agree as follows:

a) At the time COMPANY supplies compounds pursuant to Article 1, COMPANY shall forward to NIMH a data sheet for each COMPOUND giving pertinent available data as to chemical formula, structure, purity, solubility, melting point, other physical characteristics, stability, toxicity, and precautions which need to be followed in handling and storing of the COMPOUND. After authorization from the GPO, COMPANY shall ship the COMPOUND/S directly to the NIMH CONTRACTOR specified by the GPO.

b) The GPO will inform COMPANY which COMPOUNDS are new to NIMH and which submitted COMPOUNDS duplicate any COMPOUNDS previously existing in NIMH's structure-activity database.

c) NIMH will not disclose COMPANY CONFIDENTIAL INFORMATION unless required by law. Only those NIMH or NIMH CONTRACTOR employees with a need to know will have access to COMPANY CONFIDENTIAL INFORMATION.

d) NIMH shall require that COMPANY CONFIDENTIAL INFORMATION will be retained by NIMH CONTRACTORS, and shall not be released, published, or disclosed without the written consent of NIMH after consultation with COMPANY.

e) NIMH shall make no use of the COMPOUNDS and COMPANY CONFIDENTIAL INFORMATION other than for purposes stated in Article 1 without COMPANY's written permission.

f) NIMH shall return to COMPANY and eliminate from the NIMH testing process any COMPOUND that COMPANY may designate prior to commencement of CONVENTIONAL TESTS.

g) The foregoing restrictions on use and disclosure of COMPANY CONFIDENTIAL INFORMATION hereunder shall not apply to any information which was in NIMH's possession or control prior to the date of COMPANY's disclosure, or to any information which is in the public domain through no improper act on the part of NIMH, its employees or contractors, or which is available without restriction from any source, including COMPANY.

Article 3. COMPANY, in voluntarily supplying COMPOUNDS hereunder, is entitled to protection for the research and development work it has done and for any COMPANY CONFIDENTIAL INFORMATION, while NIMH has the responsibility to facilitate the development of medications for the treatment of mental disorders. Accordingly, the parties agree as follows:

a) NIMH agrees that all preexisting rights in those COMPOUNDS in which COMPANY has a proprietary interest shall remain in COMPANY. Inasmuch as this Agreement concerns only the evaluation of COMPANY's COMPOUNDS in CONVENTIONAL TESTS, NIMH recognizes that the mere performance of said CONVENTIONAL TESTS and nothing more does not constitute invention.

b) Contracts between NIMH and NIMH CONTRACTORS, carrying out CONVENTIONAL TESTS on submitted COMPOUNDS, will contain terms to implement the provisions of this Agreement relating to NIMH CONTRACTORS and to safeguard the rights of COMPANY under this Agreement.

c) NIMH shall be informed in writing whenever COMPANY desires to include NIMH DATA in any publication, and appropriate credit shall be given to NIMH.

Article 4. As soon as NIMH DATA is reported to NIMH, NIMH agrees to provide this information to COMPANY. If a COMPOUND is found to exhibit properties that suggest its potential usefulness in the treatment of mental disorders, NIMH will advise COMPANY to that effect.

Article 5. It is understood that COMPANY shall not be liable to the Government for any claims or damaged which shall result from the testing of COMPOUNDS while in NIMH's or the NIMH CONTRACTORS' custody, except if such claims or damages are the result of negligence on the part of COMPANY.

Article 6. In performing the CONVENTIONAL TESTS hereunder, NIMH and NIMH CONTRACTORS shall function independently and not as employees or agents of COMPANY.

Article 7. The construction, validity, performance, and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia.

Article 8. This Agreement shall become effective on the date hereinabove set forth.

Acceptance of the foregoing terms and conditions shall be indicated in duplicate by signatures below of the authorized representatives of each party.

COMPANY:

_____ _____
Signature Date

Name (Type or Print): _____

Title: _____

COMPANY Department: _____

COMPANY Name: _____

COMPANY Address: _____

NATIONAL INSTITUTE OF MENTAL HEALTH:

_____ _____
Authorized Official Date
NIMH/NIH

APPENDIX 3
February 22, 2002
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CONFIDENTIALITY AND NONDISCLOSURE AGREEMENT

As of this ____ day of _____, as used herein, _____ _____, is the "Disclosing Party" and the National Institute of Mental Health (NIMH), 6001 Executive Blvd. Bethesda, MD 20892, the party receiving the Confidential Information, is the "Recipient". In connection therewith, the parties agree as follows:

1. Confidential Information of the Disclosing Party may be used by the Recipient only in the review of data on a novel compound.

2. The Recipient will not, at any time, use the Confidential Information of the Disclosing Party in any fashion, form, or manner, except in furtherance of the purpose described above.

3. Each party will protect the confidentiality of the other party's Confidential Information in the same manner it protects the confidentiality of its own proprietary and confidential information of like kind. Access to the Confidential Information shall be restricted to those of each party's personnel engaged in a use permitted hereby.

4. Confidential Information disclosed hereunder shall at all times remain, as between the parties, the property of the Disclosing Party. This Agreement or any disclosure of Confidential Information grants no license under any trade secrets, copyrights, or other rights hereunder.

5. Confidential Information of the Disclosing Party may not be copied or reproduced by the Recipient without the Disclosing Party's prior written consent.

6. All Confidential Information made available hereunder, including copies thereof, shall be returned promptly to the Disclosing Party upon request of the Disclosing Party, or, at Disclosing Party's option, shall be destroyed by the Recipient.

7. Nothing in this Agreement shall prohibit or limit any party's use of information (including but not limited to ideas, concepts, know-how, techniques, and methodologies) which was (a) previously known to it, (b) independently developed by it, (c) acquired by it from a third party which was, to the Recipient's knowledge, under an obligation to the Disclosing Party not to disclose such information, or (d) which is or becomes publicly available through no breach by the Recipient of this Agreement.

8. In the event any party receives a subpoena or other validly issued administrative or judicial process demanding Confidential Information of any other party, the Recipient shall promptly notify the Disclosing Party and tender to it the defense of such demand. Unless the demand shall have been timely limited, quashed or extended, the Recipient shall thereafter be required to comply with such demand to the extent permitted by law. If requested by the party to whom the defense has been tendered, the Recipient shall cooperate (at the expense of the requesting party) in the defense of a demand. In the event the recipient National Institute of Health (NIMH) receives a request for Confidential Information under the Freedom of Information Act (5 U.S. C. 552), it will notify the Disclosing Party, and handle the request in accordance with 45 Code of Federal Regulations (CFR) 5.65.

9. Subject only to its confidentiality and non-disclosure obligations as set forth in this Agreement, each party's right to develop, use, and market products and services similar to and competitive with the Confidential Information of the other party shall remain unimpaired. Each party acknowledges that the other party may already possess or have developed products or services similar to or competitive with those of the other party disclosed in the Confidential Information.

10. No party may use the name of the other party in connection with any advertising or publicity materials or activities without the prior written consent of the other party.

11. The parties acknowledge and agree that, in the event of any breach of this agreement, the Disclosing Party might be irreparably and immediately harmed and unable to be made whole by monetary damages. It is accordingly agreed that the Disclosing Party, in addition to any other remedy to which it may be entitled at law or in equity, will be entitled to seek an injunction or injunctions to remedy breaches of this Agreement and/or to compel specific performance of this Agreement.

12. This agreement shall become effective as of the date Confidential Information is first made available to the other parties hereunder.

13. This Agreement shall be governed by Federal law. In the event of a conflict, Federal law shall control. This agreement shall be binding on each party's officers, employees, agents, successors in interest, and assigns, and shall be modified only by written agreement of the parties.

Agreed and Accepted:

_____

By: _____
(Signature)

_____
(Printed Name)

_____
(Title)

_____
(Date)

Agreed and Accepted:

National Institute of Mental Health

By: _____
(Signature)

_____
(Printed Name)

_____
_____
(Title)

_____
(Date)

ATTACHMENT 2
February 22, 2002
[Return to TOC]

EVALUATION CRITERIA FOR AWARD

A. GENERAL - BASIS FOR AWARD

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Offers form qualified HUBZone firms and small disadvantaged business concerns may have special evaluation terms (see below). The small disadvantaged business participation (SDBP) factor is explained in E. below.

Proposals are intended to be evaluated and award made after discussions with offerors, but an award may be made without discussions with offerors.

B. MANDATORY QUALIFICATION CRITERION

The qualification criterion below establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) in order for your proposal to be considered any further for award. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance

with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the Internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.
-Evidence that the Contractor's IACUC shall approve all animal procedures under this contract

C. TECHNICAL EVALUATION CRITERIA AND ASSIGNED WEIGHTS

Proposals submitted in response to this RFP will be judged solely on the written material provided by the offeror. The technical evaluation committee when reviewing the technical proposals will use the evaluation criteria below. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. The maximum score for a proposal is 100 Points.

1.	**TECHNICAL APPROACH FOR GLP TOXICITY AND SAFETY TESTING OF CNS COMPOUNDS**	**50 Points**
a.	***Demonstrated state-of-the-art quality, soundness, feasibility, and reliability of the offeror's experimental protocols and procedures for testing the toxicity and safety of CNS compounds, under GLP conditions, in acute single-dose and repeat-dose studies*** Points to consider in evaluations: • Demonstrated expertise and experience with FDA/ICH guidelines and technical requirements for toxicity and safety studies of CNS compounds for human use; confidence that offeror can comply with current GLP regulations for nonclinical laboratory studies under this contract • Quality of approach in designing toxicity and safety protocols for CNS compounds, histopathology, and preparation of reports suitable for submission as part of an IND, RDRC, or NDA application for human studies	**(35 Points)**

	As support to demonstrate your ability to perform the assays required, <u>submit the following</u>: 1) Recent examples of experimental protocols for each type of assay specified in the Statement of Work, marking out any confidential or proprietary information; if no recent examples exist, design new protocols. Protocols submitted should reflect the following assumptions: a. Assume that the compound to be tested in assays 1-3 is a novel CNS ligand intended for human PET imaging research studies. Submit protocols based on the control and 3 dose paradigm for acute toxicity studies in rats, rodents, and beagle dogs. b. Assume that the compound to be tested in assays 4-6 is a novel CNS compound intended for pilot human research studies. Submit protocols based on oral administration of the compound for 90-day repeat dose toxicity studies in rodents and beagle dogs. 2) Reports of the 2 most recent FDA data audits and inspections as documentation – if there are none to submit, provide a narrative discussion of expertise and experience with GLP studies 3) Data on the number of CNS compounds tested per year; percentage of compounds tested in which Technical Reports were submitted as part of an IND application to FDA; percentage of compounds that required additional toxicity or safety testing after FDA review of the IND application	
b.	**Data Management and Security** Points to consider in evaluations: • Quality control procedures to ensure data reliability and reproducibility • Appropriateness of plans for data management, including plans to set up and maintain a secure archive of data and specimens to assure and protect the intellectual property and confidentiality of compound data. • Plans to set up and maintain a secure electronic database of sample receipt, handling, and testing • Ability to report data to the NIMH in accordance with the Statement of Work; ***submit a copy of a Final Compound Report with your proposal***	**(15 Points)**
2.	**QUALITY OF PERSONNEL, STAFFING AND MANAGEMENT PLAN**	**35 Points**
a.	**Project Director/Principal Investigator:** Points to consider in evaluations:	**(15 Points)**

	• Demonstrated capabilities in assessing the toxicology and safety of CNS compounds • relevance and quality of recent work • documented knowledge and experience with FDA/ICH guidelines for toxicity and safety studies of CNS compounds • documented availability for proposed project in relation to other commitments • documented experience with managing similar complex projects	
b.	**Histopathologist and other key personnel:**	**(10 Points)**
	Points to consider in evaluations: • relevant experience of histopathologist and quality of recent work • relevant experience of other professional, research technical, and key support staff, and quality of recent work • documented knowledge and experience of professional staff with FDA/ICH guidelines for toxicity and safety studies of CNS compounds • documented availability for proposed project in relation to other commitments • documented experience of staff with similar projects	
c.	**Staffing Plan, Organizational Support, and Logistics:**	**(10 Points)**
	Efficient administration and staffing of the project, organizational support for the studies, and coordination of the resources to ensure time commitments for deliverables are met. Points to consider in evaluations: • appropriateness and efficiency of the staffing plan to accomplish the work; organizational chart delineating lines of authority, areas of management for specific tasks, reporting responsibilities, coordination with NIMH, and quality control procedures. • evidence that this project will have sufficient support and priority from upper level management • appropriate plan for coordination and logistics of any activities to be subcontracted.	

3.	**FACILITIES**	**15 Points**
	Documented availability and appropriateness of the facilities (office, computer, laboratory space, animal housing); equipment and resources necessary to meet the requirements specified in the Statement of Work. Points to consider in evaluations: • Adequate laboratory space, available equipment and computers (submit a floor plan that shows the location of the resources and equipment dedicated to the project) • Capacity and capability of the lab to process multiple assay requests concurrently • Appropriate animal housing facilities • On-site availability of animals (rodents, rabbits, beagle dogs, rhesus monkeys) required for toxicity and safety studies as specified in the Statement of Work • Source of animals, if not available on-site	
		100 Points

D. PAST PERFORMANCE FACTOR

See Attachment 3, Past Performance Information, for more detail.

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

Past performance will not be scored, but the Government's conclusions about overall quality of the offeror's past performance will be a factor in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered most advantageous to the Government.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

E. HUBZONE SMALL BUSINESS CONCERNS

Offer from HUBZone Small Business Concerns:

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

F. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

Offers from Small Disadvantaged Business firms:

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

G. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

Offers from Other than Small or Small Disadvantaged Business firms:

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

H. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

ATTACHMENT 3
February 22, 2002
[Return to TOC]

INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

1. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show—

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror

(and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.*

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5)Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225_17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or

disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3)Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

2. "JUST IN TIME"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall not be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit an acceptable subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Attachment 3 of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

3. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Attachment 4 of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710

(2) The small business size standard is 500 employees

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

4. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

5. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE AWARD will be made from this solicitation and that the award(s) will be made on/about 9/30/02 .

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a TERM OF 3 years, plus two, one-year options, and that incremental funding will be used [see Attachment 3, Business Proposal Instructions].

6. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

7. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

8. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

9. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in Attachment 2 of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

10. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

11. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Contracts Management Branch
National Institute of Mental Health, NIH
NSC, Rm. 6107
6101 EXECUTIVE BLVD MSC 9603
BETHESDA MD 20892- 9603

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

12. LATE PROPOSALS AND REVISIONS , HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215_1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the cover letter. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in Attachment 3.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in Attachment 3.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 4, form entitled PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 2 of this RFP.

(6) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular Purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(7) Care of Live Vertebrate Animals

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the Internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(8) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf

(9) Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) Selection of Offerors

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIMH's policy to conduct discussions with all offerors in the competitive range, NIMH reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(11) Small Business Subcontracting Plan

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in Attachment 3 of this RFP.

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in

accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment _ to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan, which is provided in Attachment 4 to this RFP.

(12) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(13) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Attachment 2, shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. Waiver of the price evaluation adjustment shall be clearly stated in the proposal.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm .

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsection(s). The applicable authorized NAICS Industry Subsection(s) for this project is (are) identified elsewhere in this RFP. Subcontractors shall provide a total target for SDB participation by the prime contractor, that includes any joint ventures and team members, as well as a total target for SDB participation. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is not in any way intended to be a substitute for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	10%	$100,000
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(14) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(15) Salary Rate Limitation in Fiscal Year 2002 *

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 – September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct

salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf

(16) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and

(ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(h) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;

(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(i) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(17) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(18) Past Performance Information

a) Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last THREE (3) contracts completed during the past THREE years and ALL CONTRACTS currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as >$500,000 .

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(19) Solicitation Provisions Incorporated by Reference , FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

c) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Attachment 2).

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points), which is based upon the information contained in the offeror's proposal.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b) The information submitted shall be at the level of detail described below.

1. Direct Labor

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. Fringe Benefits

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

5. Indirect Costs

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

6. Special Equipment

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

7. Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

8. Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities that can be devoted to the project may be appropriate.

b) Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) Performance History

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) Pertinent Contracts

Pertinent contracts are defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors, which are relevant to the ability of the offerors to perform, and are considered in the source selection process.

(5) Other Administrative Data

a) Property

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification, which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999) The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer-Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9_digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9_digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(End of Provision)

(6) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(7) Proposer's Annual Financial Report

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in Attachment 3 of this RFP.

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(8) Representations and Certifications

One copy of the Representations and Certifications (see Attachment 4) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(9) Travel Costs/Travel Policy

a) Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) Travel Policy

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in Attachment 3 of this RFP.

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

ATTACHMENT 4
February 22, 2002
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APPLICABLE RFP REFERENCES/FORMS/WEB LINKS

A. Sample Contract Format- General

The website below outlines a "typical" format for Sections B-J of a contract document. This schedule is provided for informational purposes only. The contract schedule set forth in the website below contains information pertinent to many types of R&D solicitations done at the NIH. The Schedule is not an exact representation of the proposed contract document. For example, contractual provisions pertinent to an Offeror's organizational structure (e.g., Non-Profit, Commercial) and specific costs requiring Contracting Officer prior approval will be negotiated and included in the contract.
http://ocm.od.nih.gov/contracts/rfps/SAMPKT.HTM

B. General Clauses and Provisions

The following general clauses and provisions are applicable to this specific RFP and are located on-line at the URL http://rcb.nci.nih.gov/clauses/clauses.html

Any resultant contract will include clauses applicable to your particular type of institution (e.g. educational, for-profit etc.). These clauses are provided for informational purposes only, but may be discussed during negotiations.

C. Forms, Formats And Attachments

The following items are applicable to this specific RFP and are located on-line at URL http://ocm.od.nih.gov/contracts/rfps/FORMS1.HTM under the heading Forms, Formats and Attachments.

1. SUBMIT WITH TECHNICAL PROPOSAL (with original and each copy of technical proposal)

    a. Technical Proposal Cover Sheet
    b. Summary of Current and Proposed Activities
    c. Technical Proposal Cost Summary
    d. Government Notice for Handling Proposals (as applicable)

2. SUBMIT WITH BUSINESS PROPOSAL

    (Submit with original and each copy of business proposal)

    a. Proposal Summary and Data record, NIH-2043
    b. Business Proposal Cost Information (or other Cost spreadsheet in offeror's format); must show costs and hours/percent effort, by year, by individual and cost category)
    c. Estimated Cost Per Assay Chart (attached p.68)

(Submit with the original only)

d. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original.
e. Representations and Certifications

3. OTHERS - TO BE SUBMITTED LATER:

a. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, (if required by the CO).
b. Small Business Subcontracting Plan, to be submitted as directed by the CO.

4. ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

a. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
b. Procurement of Certain Equipment, NIH(RC)-7
c. Small Business Subcontracting Plan

5. PROPOSAL INTENT RESPONSE SHEET (attached p.67)

6. ESTIMATED COST PER ASSAY CHART (attached p.68)

PROPOSAL INTENT RESPONSE SHEET
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PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **April 2, 2002**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

☐ DO INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING:

*"NIMH Program for Toxicological Evaluation of Novel Ligands"*_____
_____
_____

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

_____
_____
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

_____
_____
_____
_____

RETURN TO: National Institute of Mental Health, NIH
Contracts Management Branch
Attn: Bruce E. Anderson
Neuroscience Center Bldg., Rm. 6107
6001 Executive Blvd. (MSC 9603)
Bethesda, MD 20892-9603
FAX (301) 443-0501
ba9i@nih.gov

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ESTIMATED COST PER ASSAY CHART

Type of Tests	*Species*	*Estimated Cost Per Assay* **$**
Assay 1 - Acute toxicology testing	Rodents	
Assay 1 - Acute toxicology testing	Rabbit	
Assay 1 - Acute toxicology testing	Dog	
	Primate	
Assay 2 - Toxicokinetic studies	Rats	
Assay 3 – Acute safety pharmacology	Dog	
	Primate	
Assay 4 - Repeat dose toxicology – 30 day	Rodents	
Assay 4 - Repeat dose toxicology – 30 day	Dogs	
*Assay 5 - Repeat dose safety pharmacology	Dogs	
*Assay 6 - Mutagenicity and genotoxicity	Cell-based	

Note 1: For cost purposes, include a *separate* cost estimate for testing 1 compound in Assay 5 and 1 compound in Assay 6, but do not include these costs in the total proposed cost for the contract.

Note 2: Costs should be based upon submission of the Final Compound Report for each compound and species tested ~ 4 weeks after completion of the laboratory work specified in the protocol